

REMARKS

A. Status of the Claims

Claims 1-32 are currently pending and presented for reconsideration.

B. Claim Rejections Under 35 U.S.C. § 103(a)

The Action maintains the rejection of claims 1-32 as obvious over Wilcox (*Crop Sci.* 38:900, 1998) in view of Conway (U.S. Patent 6,140,556). Applicants respectfully traverse.

1. Claim terms are not properly interpreted in view of the Specification

Applicants note that the pending Action, for instance at page 3, asserts that soybean line C1944 (= SN30003) is an “agronomically elite” soybean plant, while pointing to the Specification at p.10, line 10, and apparently understanding that yield level is the only criterion for assessing whether a soybean cultivar or line is “agronomically elite.” Applicants traverse by again noting that whether a soybean line is considered to be “agronomically elite” is not based solely on its yield potential, but rather on a combination of agronomic traits, for instance as discussed in the Specification at page 13, line 10, and at page 38, lines 8-11. Further, Applicants again note that Wilcox 1998, cited as reference C43, does not describe C1944 as an “agronomically elite” variety, but instead as a **breeding line**, *i.e.* as germplasm for further breeding attempts.

In particular, the Specification at page 38 defines the term “agronomically elite” without even explicitly referring to yield level. Therefore, the Action’s apparent understanding of the meaning of this term is not consistent with the Specification at page 38, and the rejection made is thus improper and without basis. “Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v.*

White Consolidated Industries Inc., 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999). M.P.E.P. 2111.01 IV.

Additionally, C1944 is described by Wilcox (1998) as possessing a mean seed oil content of 18.4- 18.6% (See Wilcox, p. 900, left column, 1st and 3rd paragraphs of article), and is described in the Action at the top of page 6, as possessing an oil content of about 18.4%. This level of seed oil is clearly distinct from the presently recited mean whole seed total oil content of at least 20% and a skilled worker would clearly understand this, even though the Action does not address, at least at pages 3-6, the presence of the limitation regarding a mean whole seed total oil content of at least 20%, as found in the present claims.

Applicants also submit that an oil content of about 18.4% would not be understood in the art to include an oil content of “at least 20%” as is presently claimed. That is, such mean seed oil values are non-overlapping and clearly distinct. “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). M.P.E.P. 2143.03. Since the claim terms “agronomically elite” and “at least 20% seed oil” are not being properly interpreted in view of the teachings of the Specification and knowledge in the art, Applicants respectfully submit that the rejection is without proper support, and request that be withdrawn.

2. No expectation of success is provided for combining oil, protein, and/or yield

The Action also asserts, for instance on page 3, that C1944 has the combination of agronomic traits as the claimed invention as would any progeny or subsequent generation thereof. Applicants submit that this is mistaken, both with respect to C1944 itself, as well as with respect to “any progeny” or “any subsequent generation” at least at the present filing date. That is, any progeny of C1944 of any subsequent generation would not have been expected by a

skilled worker to routinely have the combination of agronomic traits displayed by C1944, let alone the traits as recited in the present claims, since such traits would have been expected to differ in progeny, depending on the parents of the progeny and the genetic segregation occurring at each generation, as well as any selection imposed by a breeder, further in view of the known negative correlations between the traits of mean seed oil level, mean seed protein level, and yield (*i.e.* the traits do not segregate randomly).

The Action asserts at page 4 that one of skill in the art would have had a reasonable expectation of success, in view of the combined teachings of the cited references (Wilcox, *Crop Sci.* 38:900, 1998; and Conway, U.S. 6,140,556), to produce novel soybean cultivars as claimed. Applicants respectfully submit that this assertion is **conclusory and mistaken**. No reference or other teaching is discussed which supports this assertion that there would have been any expectation of success at the present filing date, and the well-known negative correlation between the one or more of the traits of yield, mean whole seed total protein content, and mean whole seed total oil content, as discussed extensively in the Specification and in previous responses **teaches away** from such an expectation.

For instance, Conway at column 1, lines 34-37, discusses the complexity of inheritance as influencing the breeding process. Applicants note that this is discussed for “one or a few favorable genes for a highly heritable trait.” Applicants respectfully submit that the presently claimed traits were not genetically defined as the result of one or a few favorable genes, and would not have been considered to be highly heritable at least when being simultaneously or sequentially selected for within the same line, as well as when yield was also being assessed. Because the presently claimed agronomic traits were not known to be due to the presence of one or a few favorable genes for a highly heritable trait, Conway is not apt, and would not yield, to a

skilled worker, any expectation that selecting for improvements in both seed oil and seed protein, in the context of an agronomically useful yield, would routinely be successful.

In particular, as already noted, the known negative correlation between seed protein and oil content **teaches away** from an expectation of success by itself. Additionally, when combined with the results described in references such as Wilcox C43 and C83 among others, a skilled worker would not have expected that the claimed oil and protein levels could be achieved in an agronomically elite progeny plant by the end of a breeding regime. As discussed previously, even if the outlier C0 generation plant of Fig. 3 of reference C83 is understood to display the presently claimed seed protein and oil contents, it is not an agronomically elite soybean plant, its yield level was not given, and the recited seed protein and oil levels were not displayed in any C4 or C8 generation plants, which is also *prima facie* evidence that such oil and protein levels were not routinely achievable or maintainable during a breeding scheme, to produce an agronomically elite plant.

Applicants respectfully submit that instead of demonstrating obviousness, the Wilcox references (*e.g.* C43 and C83) and others show that, in spite of possessing multiple lines which, **only in hindsight**, might potentially have been used to achieve the present invention, Wilcox (or others) simply did not produce a plant, or utilize a method, as now claimed. Wilcox 1998b (*Crop Sci.* 38:1536-1540, 1998; reference C83), also shows that there would have been no expectation in the art that the presently claimed oil and protein content could be achieved, since this reference notes that **later cycles of recurrent selection displayed an even stronger inverse relationship between seed protein and oil content**, as indicated by steeper slopes of and decreased variability around regression lines in later selection cycles (*See* C83, Abstract), which teaches away from an assertion of obviousness.

Achieving both of the presently recited levels of seed protein and oil content in a single agronomically elite cultivar is thus inventive, regardless of whether one or the other had been previously achieved in **separate** lines or cultivars. Again, given the known negative correlation between seed protein and seed oil levels, these phenotypes would not be expected to segregate independently as would be needed for the Action’s assertion of predictable results to be accurate, and thus there would have been no reasonable expectation that the recited phenotypes could be achieved. Applicants therefore respectfully submit that the Action provides no reasoned basis for the rejection, and request its withdrawal.

The Action also characterizes C1944 as having an oil content that does not decrease in view of its protein content (see Action, top of page 6). Applicants submit that this represents a misunderstanding of the cited reference, which instead states that the line is “...useful for increasing seed protein while minimizing reductions in seed oil content.” However, whether oil content is understood to not decrease as stated in the Action, or if oil content is expected to decrease, albeit to a lesser extent than with some other soybean lines as Applicants submit is stated in the reference, in any event oil content is certainly not expected to increase in progeny of C1944, which would be necessary if an artisan were to achieve the presently claimed “at least 20%” seed oil content.

At page 7, the Action finds non-persuasive Applicants’ arguments regarding the distinctness of an oil content of 18.4% from an oil content of “at least 20%.” Applicants respectfully traverse. Although the Action cites M.P.E. P. 2141 (III) to support the rejection, Applicants note that this section of the M.P.E.P. also states: “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning

with some rational underpinning to support the legal conclusion of obviousness.”” *KSR International Co. v. Teleflex Inc., et al.*, 550 U.S. 398, 127 S. Ct. 1727, 82 USPQ2d at 1396.

Applicants submit that the Action provides no such articulated reasoning to substantiate an assertion that an oil content of “about 18.4%” is equivalent to one of “at least 20%”, or that “...one of ordinary skill in the art would recognize that **any desirable trait** lacking in soybean variety SN30003 could be supplemented in **any progeny** by crossing soybean variety SN30003 with another soybean plant that had the trait to produce progeny having the claimed characteristics.” [emphasis added].

Regarding the first assertion in the paragraph above, the two oil content values are distinct and non-overlapping. The second assertion is at best an oversimplification of the field of plant breeding, and is not accurate, particularly when the desirable traits are not independent, but instead may be genetically linked and/or physiologically/metabolically inter-related (which was unclear; see below) and do not segregate independently. That is, if traits are known to be negatively correlated, then a skilled worker would not routinely or predictably expect success in combining them, absent some factor such as a recombination event which might break a (non-desirable) genetic linkage, or the presence of some other genetic or environmental factor which might in some way overcome the negative correlation, and which event or factor is not discussed in the Action. In view of the above, withdrawal of the rejection is respectfully requested.

Applicants also concurrently submit a Declaration of inventor Dr. Richard Leitz under 37 C.F.R. § 1.132. This declaration makes clear that, in view of the cited references, a skilled worker would not have routinely expected that such negatively correlated traits as mean whole seed oil content, mean whole seed protein content, and yield could be combined predictably and without

undue experimentation at the recited levels, absent the teachings of the present Specification. In view of this, withdrawal of the rejection is respectfully requested.

3. Undue experimentation would have been needed: *Graham* inquiries are not resolved or addressed

Applicants further note that M.P.E.P. 2141 (III) begins “**Once the *Graham* factual inquiries are resolved**, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art...” [emphasis added]. However, Applicants respectfully submit the *Graham* inquiries have not been resolved, because, (1) as noted above, undue experimentation would be required in order to overcome or avoid the negative correlation between the recited seed oil and seed protein phenotypes, as well as the known interaction between these phenotypes and yield; and (2) the *Graham* inquiries are not addressed in the Action, and so the line of reasoning asserted to support the rejection, which requires that they be taken into account, is necessarily conclusory and logically flawed.

The basis of the negative correlation between mean seed oil content and mean seed protein content was unclear at the filing date, and even if the negative correlation were considered, only *in arguendo*, to be genetically based and due to separate but linked genes (as opposed to metabolically/physiologically based for instance in view of metabolic constraints for carbon allocation in a plant), it would have been unclear whether genetic linkage between allele(s) conferring high protein and one or more alleles conferring low oil could be broken- *i.e.* by a recombination event. Alternatively, a skilled worker could have hypothesized that at least some portion of the previously noted negative correlation could be due to a single locus or even a single gene, and thus a recombination event to overcome this might not even have been likely or possible.

Such scenarios are a further indication that **undue experimentation** would have been needed at the filing date for achieving predictability in combining the phenotypes as recited. Applicants simply do not understand how a skilled worker would have known to proceed to have “fitted the teachings...together like pieces of a puzzle” [KSR, *op cit.* at 1397; M.P.E.P. 2141 (II) (C)], when such necessary knowledge or teachings were missing from the art at the filing date. Even if some “pieces of the puzzle” were available, such as line C1944, highly skilled workers such as Dr. Wilcox did not understand how they might have been “pieced together”, and an assertion that the claimed invention is obvious thus reflects improper **hindsight** reasoning. In total and in view of the accompanying inventor’s declaration, Applicants respectfully submit that the Action’s assertion that combining the phenotypes (seed oil, seed protein, and yield) was routine, predictable, or obvious is therefore mistaken, especially since the *Graham* inquiries have not been resolved or addressed, and no proper basis for proceeding in view of M.P.E.P. 2141 (III) and, for instance, *KSR* has been provided. Withdrawal of the rejection made on this basis is therefore respectfully requested.

C. Claims Rejection Under 35 U.S.C. §102/103

The Action maintains the rejection of claims 1-12, 14, 15, 29, and 32 under 35 U.S.C. 102(b) as anticipated, or in the alternative, under 35 U.S.C. 103(a) as obvious over Wilcox (*Crop Sci.* 38:900, 1998). Applicants respectfully traverse.

As noted above in section “B,” whether a soybean line is considered to be “agronomically elite” is not based solely on its calculated yield level, but rather on a culmination of many agronomic traits including, for instance, emergence, disease resistance, vigor, and lodging resistance, among other traits, as well as yield, as discussed for instance in the Specification at page 13, line 10, and at page 38, lines 8-11. Thus, the Action’s assertion that

C1944 is “elite,” apparently based only on its yield potential, contradicts the teachings of the Specification and the definition of the term in the art, and is improper. Such an understanding also contradicts reference C44, which describes C1944 as “breeding material,” as noted in the paragraph bridging pages 13-14 in the Response filed on November 18, 2008. Further, Wilcox 1998, cited as reference C43, does not describe C1944 as an agronomically elite variety, but instead as a breeding line, *i.e.* as germplasm for further breeding attempts. Thus, the Action’s characterization of C1944 as an agronomically elite line is without basis. “Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999). M.P.E.P. 2111.01 IV.

Also, as noted in section “C” above, a mean seed oil content of “18.4%” is not equivalent to and would not encompass seed with at least 20% oil because: (1) these ranges are non-overlapping and distinct; (2) even if certain plants among a set of progeny of the C1944 line displayed 20% seed oil (which is not conceded except *in arguendo*, is not discussed in the cited reference, and is apparently only hypothesized without basis in the Action), those same plants would clearly be expected to display substantially reduced protein content and/or reduced yield, given the known negative correlation between these traits. Applicants again note that the *Graham* inquiries have not been addressed, and thus the line of reasoning based on M.P.E.P. 2141 (III) (*e.g.* Action, page 9) is unsupported as discussed above.

Further, Applicants again point to the scatter plots of Fig. 3 of reference C83. Wherein at the C8 generation, presumably closest to being “agronomically elite,” the lines displaying about 48% or more protein content, which is approximately what C1944 is described as displaying, displayed a range of about 15.5- 18% oil content, lines displaying about 45% protein content

ranged from about 18-19% oil content, and the only lines displaying 20% or greater oil content showed only about 40-43% protein. Thus, again, there is no basis to routinely expect that an individual C1944 plant or progeny, or an agronomically elite plant or progeny as described in reference C83 (which however would not be derived from line SN30003 = C1944), which might somehow display 20% mean whole seed oil content would also display 45% protein content, as described in the present Specification. Thus the rejection is without basis and its withdrawal is respectfully requested.

The Action also quotes Wilcox regarding “...increasing seed protein while **minimizing reductions in** seed oil content...” [emphasis added]. Applicants respectfully submit that this has been discussed previously, and it relates to minimizing a reduction in seed oil content, not to increasing seed oil content for instance to the level claimed (in combination with the recited seed protein content). Finally, the assertion that a skilled artisan would have had a reasonable expectation of success is made without basis, is tainted by hindsight reasoning, and is taught away-from in the art, as discussed above and in previous responses. On the contrary, the three references by Wilcox that are discussed above (*Crop Sci.* 38:900, 1998; *Crop Sci.* 38:1536-1540, 1998; *Crop Sci.* 35:1036-1041, 1995), as well as the Specification and other references previously cited therein or discussed, individually and cumulatively demonstrate that seed oil content and seed protein content are negatively correlated when paired and that if yield is added as a third selection parameter, at best only two of the three parameters would be expected to be maintained in a breeding program. In spite of developing soybean line C1944, Wilcox did not apparently pursue or achieve the present invention. Applicants respectfully submit that this is also *prima facie* evidence regarding the non-obviousness of the invention. Withdrawal of the rejection is therefore respectfully requested.

D. Conclusion

In view of the above, it is submitted that the rejections to the claims have been overcome, and the case is in condition for allowance.

The Examiner is invited to contact the undersigned agent at (214) 259-0932 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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